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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,768

01/17/2006

Bernhard Kohl

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NATH & ASSOCIATES PLLC
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EXAMINER

POLANSKY, GREGG

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

07/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,768	Applicant(s) KOHL ET AL.	
	Examiner Gregg Polansky	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,13,14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/13/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicants' response, filed 3/13/2008, to the Office Action mailed 12/13/2007 is acknowledged.
2. Applicants' Information Disclosure Statement, filed 3/13/2008, is acknowledged and has been reviewed.
3. Claims 1-5, 7, 13 are pending and presently under consideration.
4. Applicants' arguments, filed 3/13/2008, have been fully considered but they are not deemed to be persuasive. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
5. It is noted that "Exhibit B" has not been provided by Applicants as is indicated on page 7 of Applicants' arguments.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 1-5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cui et al. (Chinese Patent Publication No. 1367172).

Cui et al. teach magnesium salts of [(substituted pyridyl)methyl]sulfinyl-1H-benzimidazole derivatives, including pantoprazole, and that they can be used as proton pump inhibitors. Cui et al. teach the preparation of these compounds involves dissolving the [(substituted pyridyl)methyl]sulfinyl-1H-benzimidazole compound in alkaline

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aqueous solution adjusted to pH 9-13, followed by the drop-wise addition of a water-soluble magnesium salt solution (e.g., MgCl_2 or $\text{Mg}(\text{NO}_3)_2$) and the precipitated collected. The instant Specification discloses the compound of formula pantoprazole⁻ $\text{OH}^- \text{Mg}^{2+} \text{H}_2\text{O}$ (the elected species) as being prepared by the same reaction. Absent evidence to the contrary, the compound formed by the reaction taught by Cui et al. would have produced the same compound disclosed in the instant Specification and Claims. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to “prove that subject matter to be shown in the prior art does not possess the characteristic relied on” (205 USPQ 594, second column, first full paragraph. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) (“[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention”).

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-5, 7, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al. (Chinese Patent Publication No. 1367172, Abstract only), in view of Kohl (U.S. Patent No. 6,410,569 B1).

The teachings of Cui et al. have been presented *supra*.

Kohl teaches a pharmaceutical composition of pantoprazole magnesium dihydrate and its use in a method of treating amenable disorders of the stomach or intestine. See column 4, claims 1, 2, and 8. Kohl teaches the increased stability of the magnesium salts of pantoprazole. See column 1, last paragraph. Indeed, Kohl presents evidence of the stability of the magnesium pantoprazole salt that is comparable to that presented in the instant Specification. See Kohl reference, column 3, 1st paragraph, and instant Specification, page 5, lines 14-18. Furthermore, it appears that the pantoprazole magnesium salt taught by Hohl is identical to the pantaoprazole magnesium salt taught by Cui et al. Indeed, Applicants argue “there are no major differences between the teachings of Cui et al. and Hohl with respect to the final compounds”.

One of ordinary skill in the art at the time of the invention would have known that proton pump inhibitors were useful for the treatment of disorders of the gastrointestinal system and that effective compounds must be formulated with pharmaceutically acceptable auxiliary agents (e.g. carriers, diluents, disintegrants, etc.). The artisan

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would have found it obvious to combine the teachings of the two references cited above, motivated by the need to make pharmaceutical compositions of pantoprazole, having greater stability, for use in treating gastrointestinal disorders.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Applicants traverse both the 35 CFR 102 and 103 rejections on the grounds that allegedly, IR spectra disclosed by Cui et al. for the omeprazole magnesium salt (Cui et al. do not provide IR spectra for pantoprazole magnesium salt) do not show vibrations at around 3700 cm^{-1} and between 2300 cm^{-1} and 2400 cm^{-1} , which refer to the OH-ion. Thus, Applicants argue, the magnesium salts taught by Cui et al. do not read on the instant claims. However, no comparison can be made of IR spectra of the instantly claimed compound, since no such data has been presented by Applicants. In view of the similar reactions conditions between the prior art and the instant invention, one

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would expect the same result; that is, an identical magnesium salt of pantoprazole.

Applicants have not provided any credible evidence to the contrary.

Conclusion

11. Claims 1-5, 7, 13, and 14 are rejected.
12. No claims are allowed.
13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1611

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614